510(k) SUMMARY

Lanx Spinal Fixation System

Submitter Information

DEC 10 2009

Lanx, Inc.
390 Interlocken Crescent, Suite 890
Broomfield, CO 80021
Contact Person: Andrew Lamborne
Date Prepared: October 16, 2009

Device Identification

Proprietary Name:	Lanx Spinal Fixation System
Common Name:	Lanx SFS
Classification:	Pedicle Screw Spinal System (MNI) and/or Spinal Interlaminal Fixation Orthosis (KWP), 21 CFR 888.3070
Device Class:	Class II

Predicate Device Information

Lanx Spinal Fixation System

Intended Use / Indications for Use

The Lanx Spinal Fixation System (SFS) is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine.

The Lanx SFS is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

The Lanx Spinous Process Fusion Plate (SPFP) is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with

degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Lanx SPFP is intended for use with bone graft material, not intended for stand-alone use.

Technological Characteristics

The Lanx Spinal Fixation System consists of various screws, hooks, rods, plates, connectors, etc. that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The system components can be assembled in a variety of configurations, allowing the surgeon to tailor the construct to the particular needs of the patient.

Performance Data

Performance testing and engineering analysis was performed and submitted to characterize the modified components of the system. The Lanx Spinal Fixation System functioned as intended and the observed test results demonstrate substantial equivalence to the predicate device.

Substantial Equivalence

The additional components of the Lanx Spinal Fixation System have the same intended use, indications, technological characteristics and principles of operation as the predicate device. The modifications to the Lanx Spinal Fixation System do not raise new issues of safety or effectiveness. Testing and engineering analysis also demonstrated comparable mechanical properties to the previously cleared Lanx Spinal Fixation System. Thus, the modified Lanx Spinal System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Lanx, Inc.
% Andrew N. Lamborne
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390 Interlocken Crescent, Suite 890
Broomfield, Colorado 80021

DEC 10 2009

Re: K093285
Trade/Device Name: Lanx Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: November 24, 2009
Received: November 27, 2009

Dear Mr. Lamborne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

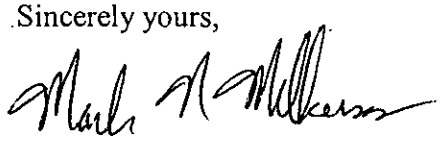
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K093285

Device Name: Lanx Spinal Fixation System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093285